


UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH DAKOTA
NORTHERN DIVISION

FILED
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CLERK

RANCHERS CATTLEMEN ACTION
LEGAL FUND; UNITED
STOCKGROWERS OF AMERICA;
HERMAN R. SCHUMACHER;
ROBERT P. MACK; ERNIE J. MERTZ;
WAYNE J. NELSON; SOUTH DAKOTA
STOCKGROWERS ASSOCIATION;
CENTER FOR FOOD SAFETY;
CONSUMER FEDERATION OF
AMERICA; CREUTZFELDT-JAKOB
DISEASE FOUNDATION, INC.;
FOOD & WATER WATCH; and
PUBLIC CITIZEN,

Plaintiffs,

vs.

UNITED STATES DEPARTMENT OF
AGRICULTURE; ANIMAL AND PLANT
HEALTH INSPECTION SERVICE;
CHARLES F. CONNER, in his capacity as
the Acting Secretary of Agriculture,

Defendants.

CIV 07-1023

MEMORANDUM OPINION
AND ORDER ON MOTION FOR
PRELIMINARY INJUNCTION

This matter is before the Court for a decision on the plaintiffs' Motion for Preliminary Injunction. The plaintiffs ("Plaintiffs") filed a Verified Complaint for Declaratory and Injunctive Relief against the United States Department of Agriculture ("USDA"), Animal and Plant Health Inspection Service ("APHIS"), and the Acting Secretary of Agriculture, to prevent implementation of a final rule published on September 18, 2007: "Bovine Spongiform Encephalopathy; Minimal-Risk Regions; Importation of Live Bovines and Products Derived From Bovines; Final Rule" 72 Fed. Reg. 53,314 (the "OTM [over thirty months] Rule"). In the OTM Rule, APHIS relaxed restrictions

on imports of live cattle and edible bovine products from “minimal risk” regions (Canada), allowing for the first time since May 2003 the importation of cattle for any purpose, provided they were born on or after March 1, 1999, and allowing imports of most edible products from Canadian cattle of any age. Plaintiffs seek to enjoin the OTM Rule, which went into effect on November 19, 2007. Shortly after the Complaint was filed, Plaintiffs filed the pending Motion for Preliminary Injunction.

The Court has considered the relevant portions of the administrative record, the parties’ briefs, the amici briefs, oral arguments presented on Tuesday, February 19, 2008, and post-hearing briefs filed by the parties and amici.¹ For the following reasons, the Motion for Preliminary Injunction will be granted in part.

I. JURISDICTION AND STANDARD OF REVIEW

The Court has jurisdiction of this proceeding under 28 U.S.C. § 1331 and 5 U.S.C. § 702. Under the Administrative Procedure Act (“APA”), the Court must not set aside agency regulations unless they are found to be arbitrary, capricious, an abuse of discretion, or otherwise contrary to law. *National Pork Producers Council v. Bergland*, 631 F.2d 1353, 1359 (8th Cir. 1980). An arbitrary and capricious agency rule exists if the agency “relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). This is a highly deferential standard of review. *Northwest Airlines, Inc. v. Goldschmidt*, 645 F.2d 1309, 1317 (8th Cir. 1981). The court cannot substitute its judgment for that of the agency, and affirmance is required if a rational basis exists for the agency’s decision. *Id.*

When considering whether to grant a preliminary injunction, the Court must consider four factors: (1) the threat of irreparable harm to plaintiffs; (2) the state of the balance between this harm

¹The Court did not consider the July 1, 2008 letter from counsel for Plaintiffs. The letter was filed before this Opinion was issued, but after the Opinion was completed.

and the injury that granting the preliminary injunction will inflict on the defendants; (3) the probability of plaintiffs' success on the merits; and (4) the public interest. *See Dataphase Systems, Inc. v. C.L. Systems, Inc.*, 640 F.2d 109, 113 (8th Cir. 1981) (en banc). The Eighth Circuit rejected a construction of the "probability of success" factor requiring that the movant prove a greater than fifty per cent likelihood that he will prevail on the merits, reasoning that:

At base, the question [of whether preliminary relief should be granted] is whether the balance of equities so favors the movant that justice requires the court to intervene to preserve the status quo until the merits are determined. The equitable nature of the proceeding mandates that the court's approach be flexible enough to encompass the particular circumstances of each case. Thus, an effort to apply the probability language to all cases with mathematical precision is misplaced.

Id. at 113. Rather, the Eighth Circuit explained that "[i]n balancing the equities no single factor is determinative." *Id.* The likelihood that the movant will prevail on the merits "must be examined in the context of the relative injuries to the parties and the public." *Id.* The Eighth Circuit provided examples of the balancing and relative importance of various factors depending upon the circumstances of the case:

If the chance of irreparable injury to the movant should relief be denied is outweighed by the likely injury to other parties litigant should the injunction be granted, the moving party faces a heavy burden of demonstrating that he is likely to prevail on the merits. Conversely, where the movant has raised a substantial question and the equities are otherwise strongly in his favor, the showing of success on the merits can be less.

Id.

II. BACKGROUND

The Animal Health Protection Act ("AHPA") gives the Secretary of the USDA broad discretion to regulate the importation of animals and animal products. It states that the Secretary "may" prohibit or restrict such importation "if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into or dissemination within the United States of any pest or disease of livestock." 7 U.S.C. § 8303(a)(1). APHIS is the agency within the USDA that regulates the importation of animals and animal products to guard against the introduction of various animal diseases in the United States. APHIS collaborates with other federal agencies to implement

a coordinated response to Bovine Spongiform Encephalopathy (“BSE”), commonly referred to as “mad cow disease.” Protection from the risks of BSE is carried out primarily by APHIS with respect to animal health, and by the USDA’s Food Safety and Inspection Service (“FSIS”) with respect to the food safety of meat.

BSE is a progressive and fatal neurological disorder of cattle. Although the agent that causes BSE has yet to be fully characterized, the theory that is most accepted in the international scientific community is that the agent is an abnormal form of a protein called a cellular prion protein. Scientists believe that the primary route of transmission between cattle requires that cattle ingest feed that has been contaminated with a sufficient amount of infected tissue from another animal. It is believed that cattle can develop BSE from exposure to as little as one milligram of infected tissue. (Doc. 19-2 at p.11.) The USDA believes that this route of transmission can be prevented by excluding potentially contaminated materials, including tissues designated as “specified risk materials” (“SRMs”), from ruminant feed.

The background of regulations developed by the USDA to prevent the spread of BSE to the United States have been set forth by the Ninth Circuit in *Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am v. United States Dep’t of Agric.*, 499 F.3d 1108 (9th Cir. 2007) (“*R-Calf II*”), and it need not be repeated at length here. In 1996, the British government discovered that consumption of BSE-contaminated meat could cause variant Creutzfeldt-Jakob Disease (vCJD) in humans. *See id.* at 1112. This is a chronic and fatal neurodegenerative disease. Approximately 200 cases of vCJD have been identified worldwide since 1996. As stated by the Ninth Circuit, “[c]hief” among the USDA’s measures to prevent BSE in the United States “was a ban on imports of all cattle products from countries where BSE was known to exist.” *Id.* Canada was added to this list in May 2003 when a cow in Alberta was diagnosed with BSE. *See id.*

In August 2003, the USDA “partially changed course and announced that certain ‘low-risk’ cattle products could be imported from Canada, including meat from cows under 30 months of age.” *Id.* APHIS completed a risk analysis regarding the possibility of resuming Canadian cattle and beef

imports. In November 2003, it announced a proposed rule creating a new category of “minimal risk” regions - - those that would present a minimal risk of introducing BSE into the United States via ruminants and ruminant products.² Canada was on the list based on its fulfillment of the three requirements for such regions. First, Canada maintained risk mitigation measures to prevent spread of BSE, including import restrictions on animals, animal products and feed, conducted surveillance for BSE at levels recommended by the Office International des Epizooties (“OIE”), also referred to as the World Organisation for Animal Health; and enforced an effective ban on feeding ruminant protein to ruminants. Second, it conducted an epidemiological investigation to confirm the adequacy of measures to prevent the further introduction or spread of BSE. Third, it took additional risk mitigation measures, as necessary, based on risk analysis of the outbreak.

The November 2003 proposed MMR Rule also proposed to permit imports from Canada of (1) cattle less than 30 months of age, and (2) meat from such cattle, subject to prescribed conditions. The rationale for this proposal was that because of the nature, incubation period, and progression of BSE infectivity, young cattle exposed to low levels of BSE will accumulate very little BSE infectivity during the first few years of life. Therefore, the USDA believed that the risk to United States livestock presented by the importation of such bovines was very low.

In December 2003, BSE was detected in a Canadian-origin cow in Washington State, likely caused by feed ingested before the Canadian feed ban went into effect. *R-Calf II*, 499 F.3d at 1112-13. In response to this discovery, on January 12, 2004, FSIS issued three interim final rules to minimize human exposure to SRMs believed to have the potential to harbor the BSE agent in infected cattle. One rule designated certain materials from cattle as SRMs, declared that SRMs were inedible, and prohibited the use of SRMs for human food. 69 Fed. Reg. 1862. It required establishments that process and slaughter cattle to develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMs. *Id.* This rule also prohibited the slaughter of non-ambulatory disabled cattle for human consumption and prescribed the proper

²This is referred to as the Minimal Risk Region rule (“MMR Rule”).

disposition of such cattle. *Id.* The other rules dealt with requirements for meat produced by advanced meat recovery systems (69 Fed. Reg. 1874), and a prohibition on the use of air injection stunning methods at slaughter because they may force pieces of the brain into the circulatory system of cattle (69 Fed. Reg. 1885). On July 13, 2007, FSIS finalized the SRM interim final rule with amendments, and affirmed without amendment the air injection stunning interim final rule. 72 Fed. Reg. 38,700 and 38,701.

In support of FSIS's July 13, 2007 final rule regarding SRMs, the agency conducted a risk assessment to develop baseline and mitigation estimates of the potential human exposure to the BSE agent. 72 Fed. Reg. at 38,703. This was an updated version of the 2001 and 2003 risk assessment models used in a previous human health risk assessment conducted by the Harvard Center for Risk Analysis of the Harvard School of Public Health and the Center for Computational Epidemiology at Tuskegee University. A peer review of the updated model ("the 2005 model") and the resulting assessment was completed in September 2005. In July 2006, FSIS published a notice in the Federal Register announcing the availability of the updated risk assessment and requesting public comment. 71 Fed. Reg. 39,282. The notice also announced a public meeting to discuss the updated risk assessment. *Id.* Plaintiff R-Calf participated in this process and filed comments with the FSIS. A discussion of the updated risk assessment is found in FSIS's July 2007 SRM final rule. 72 Fed. Reg. at 38,724-26. FSIS concluded that the results of the 2005 model demonstrated that removal of SRMs almost completely eliminates potential human exposure to the BSE agent and that the regulatory requirements for SRM removal are prudent and appropriate for preventing potential human exposure to the BSE agent. 72 Fed. Reg. at 38,726.

While FSIS was working on the SRM regulations, on March 8, 2004, APHIS reopened the comment period on the November 2003 proposed MMR rule, and also proposed to allow the import of beef from Canadian cattle thirty months of age and older, provided SRMs are removed at slaughter. AR 3837. APHIS stated:

The measures taken by FSIS do not restrict the slaughter of cattle in the United States based on the age of the animals - - *i.e.* meat from cattle 30 months of age or older will continue to be allowed into the human food supply. However, measures are in place

to ensure that SRMs from such cattle do not enter the food supply. We now believe it would not be necessary to require that beef imported from BSE minimal risk-regions [Canada] be derived only from cattle less than 30 months of age, provided equivalent measures are in place to ensure that SRMs are removed when the animals are slaughtered, and that such other measures as are necessary are in place. We believe such measures are already being taken in Canada. We invite comment from the public regarding this change to the provisions we proposed in November 2003 regarding the importation of beef.

AR 3839. The original proposal would have required beef to come from cattle that were less than 30 months of age at the time of slaughter. Plaintiff R-Calf, and 3,378 others, submitted written comments on this possible change to the proposed MMR Rule. *R-Calf II*, 499 F.3d at 1113; 70 Fed. Reg. 465. R-Calf also sought and received, on April 26, 2004, a temporary restraining order (“TRO”) against the USDA from the United States District Court in Montana. *See Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am v. United States Dep’t of Agric.*, 359 F.Supp.2d 1058, 1062 (D.Mont. 2005). The TRO prohibited the USDA from allowing importation from Canada of beef products beyond those authorized by the USDA’s action in 2003 from cattle under the age of 30 months. *See id.* On May 5, 2004 the TRO was converted into a preliminary injunction that was set to expire five days after notice of final agency action on the MMR rulemaking proposed on November 4, 2003 and reopened on March 8, 2004. *See id.*

The final MMR Rule was published by the USDA on January 4, 2005, with an effective date of March 7, 2005. *See R-Calf II*, 499 F.3d at 1113; 70 Fed. Reg. 460. It allowed imports of live Canadian cattle under 30 months of age and also allowed in Canadian beef products from cattle of all ages. *See R-Calf II*, 499 F.3d at 1113; 70 Fed. Reg. at 494. After the final rule was published, more cows in Alberta were diagnosed with BSE and, again, the USDA attributed the disease to contaminated feed manufactured before the Canadian feed ban. *See R-Calf II*, 499 F.3d at 1113. Subsequently, the USDA decided to continue the ban on beef derived from older Canadian cattle because ongoing investigations into those cases were not complete. *See* 72 Fed. Reg. at 53,316; *R-Calf*, 359 F.Supp.2d at 1068. On March 11, 2005, the USDA published a Federal Register notice suspending the section of the MMR Rule that would relax the ban on meat from cattle over 30 months old. *See R-Calf II*, 499 F.3d at 1113; 70 Fed. Reg. 12,112. The final MMR Rule was to go

into effect on March 7, 2005, but on March 2, 2005, the Montana District Court issued a preliminary injunction prohibiting its implementation. *See R-Calf*, 359 F.Supp. 2d 1058. On August 17, 2005, the Ninth Circuit reversed the preliminary injunction ruling, finding that the USDA “had a firm basis for determining that the resumption of ruminant imports from Canada would not significantly increase the risk of BSE to the American population,” and that the district court had not adequately deferred to the USDA’s determinations. *See Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am v. United States Dep’t of Agric.*, 415 F.3d 1078 (9th Cir. 2005) (“*R-Calf I*”). On remand, the district court granted summary judgment in favor of the USDA and, on August 28, 2007, the Ninth Circuit affirmed this decision on appeal. *See R-Calf II*, 499 F.3d at 1114. The Ninth Circuit stated that the additional cases of BSE-infected cows in Canada (five of the nine cases having been diagnosed “in just the past year”) were cause for concern, and that they cast doubt on the effectiveness of Canada’s feed ban. But those cases were not before the USDA during its rulemaking in 2004, and the Ninth Circuit held that the agency was entitled to rely on the opinions of its experts and other evidence that was before it at that time. *See id.* at 1117-18. The Ninth Circuit said that the “proper remedy is to petition to reopen rulemaking under 5 U.S.C. § 553(e), not to challenge the existing rule as arbitrary and capricious.” *Id.* at 1118.

This brings the Court to the OTM Rule being challenged in this case. Published on January 9, 2007, the proposed rule stated its purpose was to amend the regulations to allow importation into the United States from Canada “[l]ive bovines for any use born on or after a date determined by APHIS to be the date of effective enforcement of a ruminant-to-ruminant feed ban in the region of export; blood and blood products derived from bovines; and casings and part of the small intestine derived from bovines.” 72 Fed. Reg. at 1102. The January 9, 2007 proposed OTM Rule referred to the March 11, 2005 Federal Register notice that suspended the provision of the MMR Rule which had relaxed the ban on meat from cattle over 30 months old, stating, “[I]n March 2005, APHIS gave notice in the Federal Register that the applicability of certain provisions of the rule pertaining to bovine meat, meat byproducts, whole and half carcasses, and certain other bovine products was being delayed until further notice.” *Id.* at 1123. The proposed OTM Rule also stated, “Removal of the delay of applicability, thereby allowing importation of Canadian beef from cattle slaughtered at 30

months or older, is a decision that will be taken at the discretion of the Secretary of the U.S. Department of Agriculture.” *Id.* at 1125. The proposed OTM Rule discussed the economic effects of lifting the delay simultaneously with the publication of the final OTM Rule, but it did not discuss the safety of beef and other products from Canadian cattle over 30 months old.

The final OTM Rule was published on September 18, 2007. 72 Fed. Reg. 53,314. It was stated that, as part of the rulemaking, APHIS conducted an assessment that evaluated the animal health risk to the United States of BSE as a result of importing the “bovine commodities” considered in the rule. *See id.* at 53,315. APHIS concluded that the BSE risk to the United States is “negligible.” *Id.* The reasons given for this negligible risk were that Canada effectively enforces its feed ban, *id.* at 53,330; there is a very low level of BSE prevalence in Canada, *id.* at 53,329, and the additional, sequential barriers to the transmission of BSE (e.g., slaughter controls and dead animal disposal requirements) have a multiplicative risk-reduction effect, *id.* at 53,331.

In addition to making the risk assessment report available to the public for comments, APHIS made it available for peer review by experts in the field “to determine whether the risk assessment was scientifically sound, transparent, and consistent with international standards (e.g., those by the OIE); the application of external assessments or models was appropriate; and the assumptions were justified, supported and reasonable.” *Id.* at 53,315. Comments submitted by the public on the proposed rule were also given to the peer reviewers for their consideration. The reviewers found that the methods used in the risk assessment were scientifically sound and agreed with the conclusion that the likelihood of establishment of BSE in the United States cattle population is negligible. *See id.* at 53,316.

In the final OTM Rule published on September 18, 2007, APHIS did, in fact, lift the delay on imports of meat from Canadian cattle over 30 months old. 72 Fed. Reg. at 53,316. In the discussion regarding this, APHIS stated that the risk assessment for the final OTM Rule demonstrating a negligible risk of BSE from importing live cattle, including those over 30 months of age, supports the conclusion of the risk analysis conducted for the January 2005 final MMR Rule regarding importation

of meat and meat products derived from bovines of any age. *Id.* APHIS concluded that the BSE risk is “even lower” for the meat imports than for live bovines because the SRMs will be removed.³ *Id.*

Before the OTM Rule went into effect on November 19, 2007, Plaintiffs in this case filed their Complaint in the Northern Division of the District of South Dakota on October 24, 2007, and their Motion for Preliminary Injunction was filed on November 1, 2007. The case was transferred to this Court in the Southern Division of the District of South Dakota on December 10, 2007. An Order issued on December 13, 2007 granted Plaintiffs’ motion to extend the deadline to file their reply brief in support of the Motion for Preliminary Injunction until January 9, 2008, and directed the parties to advise the Court when they would be prepared for a hearing on the motion. The administrative record was filed on December 17, 2007. On January 10, 2008, the parties filed a “Joint Response to Order of December 13, 2007,” indicating that all counsel would be available for a hearing on the Motion for Preliminary Injunction on February 19 or February 20, 2008. The Court scheduled the hearing for February 19, 2008. Amicus curiae briefs were filed prior to the hearing by three groups: the Canadian Cattlemen’s Association, the Government of Canada and the National Meat Association, et. al. Arguments were heard from the parties at the hearing on February 19, 2008, and post-hearing briefs have been submitted by the parties and by amici. The Motion for Preliminary Injunction is now ready for ruling.

III. ISSUES PRESENTED

There are five counts in the Verified Complaint. In Count 1, Plaintiffs challenge the substantive content of the OTM Rule. Plaintiffs claim in Count 2 that Defendants acted in excess of their statutory authority in promulgating the OTM Rule. Count 3 contains allegations of procedural inadequacies in the rule-making process. Plaintiffs assert in Count 4 that Defendants failed to comply with their obligations under the National Environmental Policy Act (“NEPA”), and assert in Count 5 that Defendants failed to comply with the Regulatory Flexibility Act.

³There is no apparent basis for this conclusion because the SRMs also are to be removed from the imported live cattle at the time of slaughter in the United States.

In the Motion for Preliminary Injunction, Plaintiffs address “a fraction of the arguments that Plaintiffs believe justify overturning the OTM Rule and that would be presented in a summary judgment motion.” (Doc. 19, p. 2.) The arguments presented by Plaintiffs at this point are:

A. Plaintiffs first argue that the USDA violated the APA by failing to engage in notice and comment before lifting the ban on imports of beef from cattle over 30 months. In response, the USDA contends that the OTM beef provisions had already been subject to a thorough notice and comment opportunity before the January 2005 MMR Rule was promulgated. (As noted previously, the March 8, 2004 notice reopened the comment period on the MMR Rule and invited comment from the public specifically on imports of beef from cattle over 30 months old.) The USDA argues that further notice and comment was unnecessary in 2007 because the substance of the beef provisions did not change from the January 2005 final MMR Rule.

B. According to Plaintiffs, the USDA’s actions in removing the restrictions on Canadian imports exceed its statutory authority because they violate Congress’s mandate to “prevent the introduction into or dissemination within the United States” of BSE. 7 U.S.C. § 8303(a)(1). Defendants counter that the AHPA confers wide discretion on the Secretary to deal with imports and does not impose any requirement that all of the USDA’s actions carry no risk of disease. Investigations reveal a “negligible” risk that the OTM Rule will lead to disease in U.S. cattle, and the USDA believes the OTM Rule meets statutory requirements.

C. Plaintiffs assert that the USDA failed to consider that the different requirements for SRM disposal in the United States and Canada creates an economic incentive to ship older Canadian cattle to the United States because SRMs are banned from use for animal feed or fertilizer in Canada and disposal costs are higher. In the United States, wastes from slaughterhouses, including SRMs, can be used in non-ruminant animal feed and fertilizer. Defendants counter that Canada’s more stringent SRM requirements and its higher costs were considered in the rulemaking.

D. Next, Plaintiffs believe that the USDA has made inconsistent statements regarding BSE surveillance and testing in order to support the OTM Rule. Defendants deny that any of the statements referenced by Plaintiffs are inconsistent.

E. Plaintiffs argue that the USDA failed to respond in a meaningful way to commentators who asked the USDA to require testing of OTM Canadian cattle before slaughter. Defendants say they considered and responded to comments about testing cattle for BSE.

F. Plaintiffs contend that various provisions of the OTM Rule conflict with existing regulations. Defendants deny this allegation.

G. On November 20, 2007, Plaintiffs supplemented the record with information and argument regarding their claim in Count 4 of the Complaint that the USDA violated the National Environmental Policy Act (“NEPA”) when it promulgated the OTM Rule. Defendants claim they complied with NEPA.

The Court finds that Plaintiffs are likely to prevail on the merits of their first claim that the USDA failed to comply with the APA in promulgating the beef provisions of the OTM Rule. This conclusion requires remand to the USDA for additional administrative proceedings and, therefore, the Court will not reach Plaintiffs’ other challenges to OTM Rule at this time.

IV. LEGAL ANALYSIS

The Court’s examination of the rulemaking process reveals that the USDA failed to provide Plaintiffs and the public in general with legally sufficient notice and an opportunity to comment on its decision in 2007 to relax the ban on imports of OTM beef from Canada. All four of the *Dataphase* factors relevant to the Court’s determination whether to grant or deny a preliminary injunction weigh in favor of granting Plaintiffs’ request on this issue.

A. Plaintiffs Have Shown a Substantial Likelihood of Success on the Merits

The issue for this Court's determination is whether the Plaintiffs are likely to prevail on the merits of their claim that the September 18, 2007 OTM beef provisions should have been subject to a fresh notice and comment procedure under the APA.⁴ In their post-hearing brief, Defendants offer four reasons why they were not required to provide another round of notice and comment. First, they argue that the notice and comments regarding the January 2005 OTM beef provisions which occurred in November 2003 and March 2004 were enough because the January 2005 OTM beef provisions were never "repealed" after that. Second, Defendants assert that they simply "delayed" implementation of the January 2005 OTM beef provisions, and those provisions were not changed when they were implemented in the September 2007 OTM Rule. Third, they state that lifting the delay and announcing the new effective date for the January 2005 OTM beef provisions was a purely procedural matter exempt from APA notice and comment requirements. Finally, Defendants contend that R-Calf had actual notice of the January 2005 OTM beef provisions and the lifting of the delay.

The Court is not persuaded by Defendants' characterization of its actions. The effective date of a rule generally is more than procedural and its suspension or delay usually is subject to rulemaking. *See, e.g., Natural Res. Def. Council, Inc. v. United States EPA*, 683 F.2d 752, 761-762 (3d Cir. 1982) (holding "an effective date is 'part of an agency statement of general or particular applicability and of future effect'" within the definition of "rule" under 5 U.S.C. §551(4)); *Cf. Envtl. Def. Fund, Inc. v. EPA*, 716 F.2d 915, 920 (D.C. Cir. 1983) ("The suspension or delayed implementation of a final regulation normally constitutes substantive rulemaking under [the] APA

⁴Pursuant to section 553 of the APA, there are three basic requirements for agency rulemaking: first, the public must be given notice of the proposed rulemaking; second, the public must be given an opportunity to comment on the proposed rule, either orally or in writing; and third, the agency must include with the final rule a statement of the rule's basis and purpose. Specifically, the Act requires that "[g]eneral notice of proposed rule making shall be published in the Federal Register," and that "[t]he notice shall include ... either the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553(b). After such notice has been provided, "the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation." 5 U.S.C. § 553(c). When the final rules are promulgated, the agency is obligated to "incorporate in the rules adopted a concise general statement of their basis and purpose." *Id.*

. . . .”); *Env'tl. Def. Fund, Inc. v. Gorsuch*, 713 F.2d 802, 816 (D.C. Cir. 1983) (holding an agency decision effectively suspending duly promulgated regulations constitutes rulemaking subject to notice-and-comment requirements). In *Public Citizen v. Steed*, 733 F.2d 93 (D.C. Cir. 1984), the court found an “indefinite suspension does not differ from a revocation simply because the agency chooses to label it a suspension. Although the agency’s characterization may provide some guidance in determining the nature of the challenged action, it is the substance of what the [agency] has purported to do and has done which is decisive.” *Id.* at 98 (internal quotations omitted).

The decisions relied on by Defendants for the proposition that a temporary postponement of an effective date is not rulemaking and that implementation can be virtually automatic once the delay is lifted, are distinguishable. See *Am. Fed’n of Gov’t Employees, AFL-CIO v. Office of Pers. Mgmt*, 821 F.2d 761, 764 (D.C. Cir. 1987); *State of La. v. Mosbacher*, 1989 WL 87616, *6 (E.D.La. Aug. 1, 1989). In both cases, the delay and the lifting of the delay were the result of Congressional action not requiring further agency action. Those are not the circumstances in the present case. Here, the agency rather than Congress decided to delay implementation of the OTM beef provisions. The Defendants’ own belief in the importance of a more thorough investigation prior to implementing the OTM beef provisions is reflected in the USDA’s decision in March 2005 to delay implementation to “give Department officials the opportunity for further review and consideration of the specified provisions,” 70 Fed.Reg. at 12,113, and to complete ongoing investigations into the recent finds of BSE in Canadian cattle, 72 Fed.Reg. at 53,316. Defendants’ own record reveals that the decision to implement the OTM beef provisions after reconsideration was more than purely procedural, and that the OTM beef provisions merited further notice and comment. See, e.g., *Gorsuch*, 713 F.2d at 817 (EPA’s postponement of effective date of final rules was a reversal of course constituting a “danger signal,” requiring closer scrutiny of agency’s compliance with APA).

Before implementing the OTM beef provisions in 2007, the USDA did not reveal the results of the investigations done after March 2005 which renewed the USDA’s confidence in the regulations, or otherwise explain the bases for implementing the provisions 32 months after they were first proposed. There is no discussion about the effect the BSE cases found in Canadian cattle born

after the effective date of the feed ban would have on the OTM beef provisions. The Court could not find an explanation why imports of live cattle are limited to those born after the effective date of the feed ban but meat from cattle born before that date can be imported. Plaintiffs accurately state that “[a] key assumption underlying USDA’s justification for allowing any imports from Canada had consistently been that they would come from Canadian cattle with a low likelihood of BSE infection because those cattle were subject to a ban on ruminant protein in cattle feed.” (Doc. 117, p. 5.) In regard to the OTM beef provisions, it appears that the USDA relied on the evidence that was in the record from the original notice and comment proceeding years earlier. In light of the new cases of BSE in Canada and the dire consequences that would result from a BSE outbreak in the United States, relying on an old record and simply lifting the delay on imports of OTM beef, without more, does not reflect reasoned decision-making. *Cf. Action on Smoking and Health v. CAB*, 713 F.2d 795, 800 (D.C. Cir. 1983) (“Although the Administrative Procedure Act does not establish a ‘useful life’ for a notice and comment record, clearly the life of such a record is not infinite.”)

The USDA now says the results of the FSIS’s risk assessment indicating that removal of SRMs almost completely eliminates potential human exposure to the BSE agent, published in July 2007 with its SRM final rule, would be applicable for all beef products whether derived from cattle under or over 30 months.⁵ Even if this is true, it does not justify the USDA’s decision because the FSIS risk assessment was not referred to as a basis for implementing the OTM beef provisions in 2007. *See, e.g., City of Brookings Mun. Tel. Co. v. FCC*, 822 F.2d 1153, 1165 (D.C. Cir. 1987) (“Post hoc rationalizations advanced to remedy inadequacies in the agency’s record or its explanation are bootless.”). If the USDA relied on research done in conjunction with the SRM rule in deciding to implement the OTM beef provisions, that fact should have been disclosed to the public. *See, e.g., Solite Corp. v. United States EPA*, 952 F.2d 473, 484 (D.C.Cir.1991) (“An agency commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary.”); *see also Air Transp. Ass’n of Am. v. FAA*, 169 F.3d 1,

⁵Plaintiffs assert that none of the USDA’s assessments addressed the risk of BSE contamination in beef from cattle that were exposed to possible BSE-infected feed. Plaintiffs say they would have provided information on this issue had they been given the opportunity.

7 (D.C.Cir.1999) (“[T]he most critical factual material that is used to support the agency's position on review must have been made public *in the proceeding* and exposed to refutation.” (quoting *Ass'n of Data Processing Serv. Orgs., Inc. v. Bd. of Governors of the Fed. Reserve Sys.*, 745 F.2d 677, 684 (D.C.Cir.1984))).

The procedural safeguards of the APA help ensure that government agencies are accountable and their decisions are reasoned. *See Am. Bus. Ass'n v. United States*, 627 F.2d 525, 528 (D.C.Cir.1980); *Rodway v. United States Dep't of Agriculture*, 514 F.2d 809, 817 (D.C.Cir.1975) (APA's purpose is to cause agency to respond to comments in a reasoned manner and explain how agency resolved problems). The Third Circuit stated in *New Jersey v. Dep't of Health and Human Servs.*, 670 F.2d 1262 (3d Cir.1981):

The APA notice and comment procedures exist for good reason: to ensure that unelected administrators, who are not directly accountable to the populace, are forced to justify their quasi-legislative rulemaking before an informed and skeptical public. When these procedures are not followed in situations where they are in fact applicable, a court promotes neither the agency's ultimate mission nor respect for the law by ignoring the agency's indiscretion or condoning the agency's shortcut.

Id. at 1281. In the present case, the fact that thousands of comments were made in response to the OTM beef provisions when APHIS reopened the comment period on March 8, 2004 illustrates that the notice and comment procedure was a vital part of the USDA's rulemaking. The USDA's failure to explain why the OTM beef provisions were implemented in 2007 after its decision not to implement them in 2005 prohibits this Court from concluding that a reasoned basis for the decision existed in 2007. *See, e.g., Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 48 (“[A]n agency must cogently explain why it has exercised its discretion in a given manner.”). Because the USDA failed to initiate new rulemaking before allowing importation of beef from Canadian cattle of any age, the Court must remand to the USDA to provide notice and comment on the OTM beef provisions as required by the APA.

Notice

Defendants argue that R-Calf and other interested parties had actual notice of the OTM beef provisions and knew that lifting the delay on imports of Canadian beef from cows of any age was on the table during rulemaking for the OTM Rule. There is no dispute that the USDA provided notice and secured comments before the initial issuance of the OTM beef provisions in the January, 2005 MMR Rule. As noted previously, the January 9, 2007 proposed OTM Rule referred to the March 11, 2005 Federal Register notice that suspended the provision of the MMR Rule which had relaxed the ban on meat from cattle over 30 months old, stating, “[I]n March 2005, APHIS gave notice in the Federal Register that the applicability of certain provisions of the rule pertaining to bovine meat, meat byproducts, whole and half carcasses, and certain other bovine products was being delayed until further notice.” The proposed OTM Rule also stated, “Removal of the delay of applicability, thereby allowing importation of Canadian beef from cattle slaughtered at 30 months or older, is a decision that will be taken at the discretion of the Secretary of the U.S. Department of Agriculture.” The proposed OTM Rule discussed the economic effects of lifting the delay simultaneously with the publication of the final OTM Rule, but it did not discuss the safety of beef and other products from Canadian cattle over 30 months old.

The Court agrees that this placed Plaintiffs on notice that the USDA was contemplating reinstatement of the OTM beef provisions, but the USDA did not provide any information that would allow for useful criticism after a gap of nearly three years since the previous notice and comment on the OTM beef provisions. As stated above, the USDA had acknowledged that it needed to consider new information from its investigations in order to ensure the appropriateness of the OTM beef provisions. The public needed to be notified of the USDA’s findings and the impact of those findings, as well as given an opportunity to comment on the new information or to provide additional information. Thus, the Court cannot say that notice was adequate. *See, e.g., Arlington Oil Mills, Inc. v. Knebel*, 543 F.2d 1092 (5th Cir. 1976) (rejecting Secretary's contention that plaintiffs' actual notice that March differentials were being reconsidered constituted APA compliance; plaintiffs had been prevented from participating in the decision making process).

B. Plaintiffs Have Demonstrated Irreparable Harm

Next the Court considers whether Plaintiffs have demonstrated they will suffer irreparable injury if the Court declines to issue a preliminary injunction. Financial harm without more cannot constitute irreparable injury unless it threatens the very existence of the movant's business. *See, e.g., Packard Elevator v. I.C.C.*, 782 F.2d 112, 115 (8th Cir. 1986).

Plaintiffs claim that United States cattle producers will suffer an economic loss from imports of cheap Canadian cattle and beef for which there is little market outside Canada. Plaintiffs further assert that the general public in the United States, consumers of beef, are being exposed to meat that has a higher risk of BSE, thus there is a higher risk of people contracting vCJD in the United States. The Court finds that the last assertion weighs in favor of injunctive relief. Defendants acknowledge that there is a risk, however slight, that BSE-infected tissue would reach the human food supply in the United States and lead to vCJD, a chronic and fatal neurodegenerative disease. Plaintiffs contend that, had they had the opportunity to comment on the OTM beef provisions, they could have shown that allowing imports of beef from cattle born before the effective date of the Canadian feed ban presents a very different risk profile than that considered by the USDA.

C. The Balance of Harms and Public Interest Favors Granting the Preliminary Injunction

The two remaining *Dataphase* considerations - the balance of harms and the public interest - favor granting relief at this time. The balance of harms analysis examines the harm of granting or denying the injunction upon both of the parties to the dispute and upon other interested parties, including the public. *See Pottgen v. Missouri State High Sch. Activities Ass'n*, 40 F.3d 926, 929 (8th Cir. 1994). Any harm to the USDA by requiring notice and comment on the OTM beef provisions is slight in light of the substantial impact that importation of BSE-infected meat could have in the United States. Leaving the regulations in place during the pendency of the rulemaking proceedings will alleviate most of the potential harm to Defendants, and the USDA's discretion to regulate the importation of animals and animal products will not be impeded. The public interest will be furthered by allowing public participation in the rulemaking process to ensure that the USDA carefully and fairly considers all aspects of the important decision

to allow importation of beef from Canadian cattle of any age. Because the balance of all four *Dataphase* factors weighs in favor of issuing a preliminary injunction, Plaintiffs' request will be granted.

D. Bond Requirement

The Federal Rules of Civil Procedure require the movant to give security for the issuance of a preliminary injunction. See FED.R.C IV.P. 65(c). "Although [the Eighth Circuit] allow[s] the district court much discretion in setting bond, [it] will reverse [the district court's] order if it abuses that discretion due to some improper purpose, or otherwise fails to require an adequate bond or to make the necessary findings in support of its determinations." *Hill v. Xyquad, Inc.*, 939 F.2d 627, 632 (8th Cir. 1991).

Plaintiffs ask that no security, or only a nominal amount, be required because Plaintiffs are non-profit organizations and individual ranchers attempting to further the public interests and the goals of AHPA. Defendants make no argument to the contrary. In the absence of any showing that security is necessary, the Court will not require a bond.

V. REMEDY

The Court rejects Defendants' argument that "it is a commonsense proposition that the Court could not remand the rule to USDA for additional notice and comment at the preliminary injunction stage." (Doc. 124, p. 15.) *Cf. Mental Health Ass'n of Minnesota v. Heckler*, 720 F.2d 965 (8th Cir. 1983) (affirming with modifications preliminary injunction issued by district court enjoining Secretary's procedures used to make disability determinations). The preliminary injunction issued by the district court in *Heckler* included a remand to the Secretary to publish new rules for notice and comment, as required by the APA prior to adoption. *See Mental Health Ass'n of Minnesota v. Schweiker*, 554 F.Supp 157, 169 (D.Minn. 1982). This was affirmed by the Eighth Circuit. *See Heckler*, 720 F.2d at 974. The Court could better understand Defendants' argument if this decision on Plaintiffs' motion for a preliminary injunction was made hastily and on less than a full record, but that is not the case. The entire administrative record was filed with the Court, and the

parties and amici have been given ample time and opportunities to advise the Court of all things to be considered in regard to the motion. In light of the Eighth Circuit's clear directive that, with some narrow exceptions, courts may not consider any evidence beyond the administrative record when reviewing agency action, *R-Calf II*, 499 F.3d at 1114-15, Defendants' argument that the Court must wait until the summary judgment stage to decide if the USDA violated the APA, is somewhat disingenuous. Defendants have had as adequate an opportunity to brief and argue this issue as they would have on summary judgment, and Defendants do not claim there is some extra-record evidence not available during the preliminary injunction proceedings that would be presented to the Court in a summary judgment motion.

The Court is aware that in formulating equitable relief it "must proceed gingerly and not encroach on traditional administrative practices." *Heckler*, 720 F.2d at 972. Under Supreme Court precedent, where a fuller explanation of the agency's reasoning is needed, remand is the preferred action. *See Pension Benefit Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 654 (1990). In *United States Steel Corporation v. EPA*, 649 F.2d 572 (8th Cir.1981), the Eighth Circuit reviewed a challenge to the EPA's adoption of a final rule establishing state-wide air quality designations. The EPA adopted the designations after invoking the good faith exception to the APA, 5 U.S.C. § 553, and dispensing with prior notice and comment. The EPA instead offered to receive public comment for sixty days after promulgation. *See id.* at 574-75. The Eighth Circuit held that the EPA erred by failing to provide advance notice and comment. The Eighth Circuit noted that the sixty day post hoc comment period was an inadequate substitute for prior notice and comment when there was no indication that the agency would thereafter consider revising the regulations: "After the final rule is issued, the petitioner must come hat-in-hand and run the risk that the decisionmaker is likely to resist change." *Id.* at 576 (quoting *Sharon Steel Corp. v. EPA*, 597 F.2d 377 (3rd Cir.1979)). Rather than vacate the EPA's air quality designations, the Eighth Circuit left them in place pending further administrative proceedings. The case was remanded to the EPA to afford the petitioners notice and an opportunity to comment on the new proposed designations. The EPA was ordered to "promptly" consider the comments and to substitute any revised designations for the existing ones. *See id.* at 577.

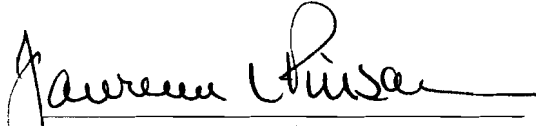
The Court will remand this case to the USDA to provide notice and comment on the OTM beef provisions, but no provisions of the OTM Rule will be vacated. Plaintiffs' remaining claims will be stayed pending administrative action. The substance of the OTM Rule may be different after further administrative proceedings, but Plaintiffs will not be precluded from reasserting their challenges to the merits of the OTM Rule at a later date, if necessary. Accordingly,

IT IS ORDERED:

1. That Plaintiffs' Motion for Preliminary Injunction, Doc. 19, is granted in part.
2. That the case is remanded to the USDA to promptly provide notice and comment on the OTM beef provisions, to consider comments made by Plaintiffs and other interested parties, and to revise any provisions of the OTM Rule it deems necessary.
3. That the remainder of the case is stayed during the administrative proceedings on remand. The parties shall submit quarterly updates to the Court regarding the status of the administrative proceedings.

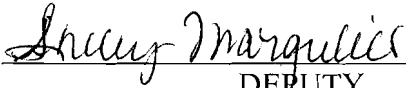
Dated this 3rd day of July, 2008.

BY THE COURT:


Lawrence L. Piersol
United States District Judge

ATTEST:

JOSEPH HAAS, CLERK

BY: 
DEPUTY